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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,932	01/23/2004	Gerald R. Heller	760-80 CPA/CON	7855

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EXAMINER	
VU, QUYNH-NHU HOANG	
ART UNIT	**PAPER NUMBER**
3763	
MAIL DATE	**DELIVERY MODE**
05/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,932	HELLER ET AL.	
	Examiner	Art Unit	
	QUYNH-NHU H. VU	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Amendment filed on 4/18/08 has been entered.

Claims 10-18 are present for examination.

Claims 1-9, 19-22 are cancelled.

Applicant's arguments filed on 4/18/08 have been fully considered but are not persuasive. Therefore, claims 10-18 are rejected in the same ground rejections as set forth in the office action mailed 11/01/07.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-12, 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donadio, III et al. (US 5,741,429) in view of Sharkaway (US 5,021,044).

Donadio discloses, Figs. 12-13, a catheter system comprising: a guide wire 95; a catheter 20 including a lumen defining an internal diameter; a catheter 20 including a lumen defining an internal diameter; an adapter (including 96 and 93) selective position able within the lumen of the catheter, the adapter including an external diameter substantially equal to the internal diameter of the lumen of the catheter (col. 16, lines 35-40); the adapter further including a lumen defining an internal diameter; the guide wire accommodated in side the lumen of adapter.

Donadio does not disclose the guide wire having two different diameters, a first external diameter and a second external diameter smaller than the first diameter; the lumen of the adapter defining an internal diameter substantially equal to the external diameter of the guide wire.

Sharkaway shows that a guide wire 15 having one of two different diameters, a first external diameter (a proximal portion of guide wire 15) and a second external diameter (a distal portion of guide wire 15) smaller than the first diameter (see Fig. 1).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Donadio with a guide-wire having different diameter, as taught by Sharkaway, in order to provide a stiffness enough to penetrate the blood vessel and to prevent kinking. For example, if the diameter of guide wire is too small, it would not be stiff enough to guide a catheter into the blood vessel and kinking will occur. If the diameter of guide wire is too big same diameter, then it would not be flexible than the guide wire with larger diameter at proximal portion and decreasing the diameter to the distal portion.

Additionally, Donadio further discloses that: in order to make guide wire steerable, the core wire has a series of elaborate tapering schemes to vary the stiffness and flexibility to various portion of the guide wire (col. 15, lines 4-8). Therefore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to recognize that in order to make guide wire steerable and vary the stiffness, the guide wire must vary diameter such as the diameter of guide wire at proximal portion must be larger than the diameter of guide wire at the distal portion. In other words, the diameter of guide wire will be larger at proximal end and start decreasing to the distal end.

Since the guide wire varies diameter, therefore, the internal diameter of the lumen of the adapter must be change and substantially equal to the external diameter of the guide wire so that to provide interference fit to supporting, increasing the stiffness, flexibility and prevent kinking during its insertion into the blood vessel (also see col. 1, lines 35-40).

Regarding claim 11, the adapter is removable slidably within the lumen of the catheter.

Regarding claim 12, the adapter extends beyond the length of the catheter, the portion extending beyond the catheter being adjustable by slidably positioning the adapter within the lumen of the catheter (Figs. 12-13).

Regarding claim 14, since the invention of Donadio relates to flexible catheters, balloon catheters (col. 1, lines 10-15), it must include an expandable balloon portion.

Regarding claim 18, Donadio discloses the claimed invention except for the lumen of the catheter is about 0.0035 inches and the lumen of the adapter is about 0.018 inches. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide the values listed above, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Donadio, III et al. (US 5,741,429) in view of Sharkaway (US 5,021,044) and further in view of Sylvanowicz (US 5,267,982).

Donadio in view of Sharkaway disclose the invention substantially as claimed. Donadio does not disclose the adapter extending beyond the length of the catheter includes a flexible tapered tip.

Sylvanowicz discloses, Figs. 9-11, the adapter extending beyond the length (50) of the catheter 60 or 52 include a flexible tapered tip 54.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Donadio in view of Sharkaway with a flexible tapered tip, as taught by Sylvanowicz, in order to provide the flexibility during its insertion into the blood vessel.

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donadio, III et al. (US 5,741,429) in view of Sharkaway (US 5,021,044) and further in view of Leoffler (US 5,891,154).

Donadio in view of Sharkaway disclose the invention substantially as claimed. Donadio does not disclose the catheter includes a radially expandable stent.

Leoffler discloses a catheter includes a stent 16 positioned about an expandable balloon portion 14. Also, it is well known in medical art, especially in percutaneous transluminal coronary angioplasty (PTCA) that the catheter includes an expandable stent to expand and hold the damaged artery.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Donadio in view of Sharkaway with a stent, as taught by Leoffler, in order to expand and hold the damaged artery.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,692,482. Although the conflicting claims are not identical, they are not patentably distinct from each other because the device of instant claims are fully disclosed and covered by the claims in the Patent No. 6,692,482.

Response to Arguments

Applicant's arguments filed 4/18/08 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the two distinct guide wires having different diameters along the length thereof) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It is noted that the recitation "guide wire having either one of two different external diameters along a length thereof, a first external diameter and a second external diameter smaller than said first diameter" can be interpreted as a single guide wire itself has two different diameters in longitudinal sequence, which is shown in the Sharkaway reference.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763